

**K090689 QUADROX-I SMALL ADULT WITH AND WITHOUT
INTERGRATED ARTERIAL FILTER WITH SOFTLINE COATING,
MODELS HMO 50000, HMO 51000**

Oct 29, 2009
227 days to decision

K090689 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k090689/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 16, 2009
Decision date	Oct 29, 2009
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Maquet Cardiopulmonary, AG
Location	Fairfield, IA, US
Contact	INGRID RICHTER
510(k) history	44 submissions · 44 cleared · 2005-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k090689/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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